

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY  
CAMDEN VICINAGE**

**IN RE: VALSARTAN, LOSARTAN,  
AND IRBESARTAN PRODUCTS  
LIABILITY LITIGATION**

**This Document Relates to All Actions**

MDL No. 2875

Honorable Robert B. Kugler,  
District Court Judge

Honorable Karen Williams,  
Magistrate Judge

**MANUFACTURER DEFENDANTS' SUR-REPLY TO PLAINTIFFS'  
MOTION FOR LEAVE TO AMEND MASTER COMPLAINTS**

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## I. INTRODUCTION

This Court’s prior MTD Opinions and MTD Orders<sup>1</sup> afforded Plaintiffs a limited opportunity to amend their Master Complaints to address identified pleading deficiencies—*not* to seek reconsideration of unfavorable rulings or to add new theories. Yet Plaintiffs’ Reply Memorandum of Law in Further Support of Their Motion for Leave to Amend [ECF No. 1382] (the “Reply”) repeatedly ignores the Court’s clear guidance, reargues multiple rulings decided against Plaintiffs, and asserts several new claims and theories. Plaintiffs are not free to ignore this Court’s previous rulings in an attempt to use Rule 15(a) as a reset button, and should not be rewarded for doing so. Plaintiffs’ efforts to alter and exceed the Court’s rulings reinforces the futility of Plaintiffs’ non-conforming amendments.

Plaintiffs’ Reply impermissibly attempts to reargue at least four issues the Court already decided. In direct contravention of MTD Opinions and Orders 2, 3, and 6, Plaintiffs: (1) assert standing to pursue claims under the laws of states in which they do not reside and were not injured; (2) assert standing to pursue claims against Defendants to whom no injury is traceable; (3) argue that privity is a fact question rather than a pleading requirement for breach of implied warranty in twelve

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<sup>1</sup> Capitalized terms have the same meaning here as in the Manufacturer Defendants’ Opposition to Plaintiffs’ Motion for Leave to Amend Master Complaints [ECF No. 1277] (the “Opposition” or “Opp.”).

states; and (4) dispute the need to allege facts demonstrating the absence of an adequate legal remedy to plead unjust enrichment in thirteen states. Plaintiffs have failed to satisfy the reconsideration standard or to supply a valid legal justification for any amendment contrary to the Court’s earlier rulings.

The Reply also inserts new claims into these proceedings. Plaintiffs belatedly propose to add state Products Liability Act (“PLA”) claims to the PELMC and PMMMC, but the new claims are in many instances not cognizable and Plaintiffs still fail to exclude subsumed common law claims. Additionally, the Reply skates past Plaintiffs’ improper assertion of a new “official compendium” theory of liability, mischaracterizing the amendment as nothing more than “additional facts and clarifications” and ignoring the absence of any legal basis for the new theory.

For these reasons, the Manufacturer Defendants request that the Court either deny Plaintiffs’ Motion to Amend or limit it as set forth in the Opposition.

## **II. ARGUMENT**

### **A. Plaintiffs Still Lack Standing to Assert Claims Under the Laws of States in Which They Do Not Reside and Were Not Injured**

MTD Opinion 2 squarely held the named Plaintiffs lack standing “to assert claims under the laws of states where they do not reside and were not injured[.]” (MTD Opinion 2 at 19). The PELMC and PMMMC defy this ruling, continuing to assert claims for breach of express and implied warranty and violation of state consumer protection laws under the laws of all fifty states, Washington, D.C., and

Puerto Rico. (*See* PELMC ¶¶ 629, 641, 648, 667, 745, 763; PMMMC ¶¶ 641, 662).<sup>2</sup>

The Reply struggles to justify its inclusion of these dismissed claims, reasserting two points Plaintiffs already lost in MTD Opinion 2: (1) that Plaintiffs have standing to represent “absent class members” from other states; and (2) that this question is one of predominance to be decided “at the class certification stage.” (Reply at 14-20). Plaintiffs insist that they “accept” the Court’s ruling in MTD Opinion 2 and wrongly assert that their amendments “present a different situation” because Plaintiffs only seek to represent “persons in states whose laws do not conflict with” the laws of Plaintiffs’ home states—notwithstanding that Plaintiffs continue to assert their claims under the laws of *every* state. (*Id.* at 15-16).

There is nothing “different” about this “situation.” Plaintiffs’ own redlines confirm that their out-of-state allegations are materially unchanged from those the Court previously dismissed for lack of standing. (*See* ECF No. 1382-5 ¶¶ 629, 641, 648, 667, 745, 763; ECF No. 1382-7 ¶¶ 641, 662). Plaintiffs still seek, as they did before, to represent putative class members from all states, including those in which

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<sup>2</sup> The Reply attaches proposed updated versions of the PPIMC, PELMC, and PMMMC. *See* Reply Exs. A-1, A-2, B-1, B-2, C-1, C-2 [ECF Nos. 1382-1, 2, 4, 5, 6, 7]. The Manufacturer Defendants join in and incorporate by reference the Pharmacy Defendants’ arguments in their sur-reply that these new proposed versions of the Master Complaints are improper and should be stricken. Nevertheless, out of an abundance of caution, citations in this sur-reply correspond to the versions of the Master Complaints filed as exhibits to the Reply.

they do not reside and were not injured. (*See id.*). And there is nothing new about Plaintiffs' arguments. They made the same two arguments in opposing Defendants' motions to dismiss. (*See* ECF No. 577 at 38-39). Plaintiffs even cite many of the same authorities for the second time. (*See id.* (citing *Neale*; *Langan*; *Rolland*; *Gress*; *In re Prudential*)). The Reply simply repackages the same arguments into a lengthier exposition with additional cases in the hopes of achieving a different result.

Plaintiffs' *de facto* request for reconsideration does not satisfy the "high" standard of demonstrating that the Court "overlooked" any legal issue that "may alter the disposition" of MTD Opinion 2, or "the need to correct a clear error of law or fact or to prevent manifest injustice." *K.J. v. Greater Egg Harbor Reg'l High Sch. Dist. Bd. of Educ.*, No. CV 14-145, 2020 WL 3542305, at \*1 (D.N.J. June 30, 2020). Plaintiffs simply want another bite of the apple on an unfavorable ruling. The Court has previously declined to reconsider its MTD Opinions in the absence of any "overlooked" legal issue, and should do the same here. (*See* ECF No. 725).

Even if the Court were inclined to take another look at out-of-state standing, its decision is correct. The Reply conspicuously omits the numerous rulings in this District favoring MTD Opinion 2 and holding that putative class plaintiffs lack standing to assert claims under the laws of states where they do not reside and were not injured. *See, e.g., Ponzio v. Mercedes-Benz USA, LLC*, 447 F. Supp. 3d 194, 222-23 (D.N.J. 2020) (reviewing "unresolved" split among district courts and concluding



that plaintiffs “lack standing to assert claims on behalf of unnamed plaintiffs in jurisdictions where Plaintiffs have suffered no alleged injury”); *In re Insulin Pricing Litig.*, No. 3:17-CV-0699-BRM-LHG, 2019 WL 643709, at \*17 (D.N.J. Feb. 15, 2019) (“[D]istrict courts within the Third Circuit and throughout the nation have held that named plaintiffs in a class action ‘lack standing to bring claims on behalf of putative classes under the laws of states where no named plaintiff is located and where no named plaintiff purchased the product at issue.’”) (citation omitted); *see also, e.g., Cooper v. Medimetriks Pharms., Inc.*, No. 18-11987, 2019 WL 1370414, at \*4 (D.N.J. Mar. 25, 2019); *In re Magnesium Oxide Antitrust Litig.*, No. 10-cv-5943, 2011 WL 5008090, at \*25-26 (D.N.J. Oct. 20, 2011).

Plaintiffs’ string-citation of cases on the other side of this split is unpersuasive. Contrary to the Reply, *Rickman v. BMW of North America*, No. CV 18-4363(KM)(JBC), 2020 WL 3468250 (D.N.J. June 25, 2020), is neither the “most recent” decision on this issue nor the most persuasive. *Rickman* declined to decide out-of-state standing, finding it “more prudent” to wait for class certification because the issues “might be rendered moot.” *Id.* at \*11. But Article III standing is not a matter of prudence; it “is essential to federal subject matter jurisdiction” and is thus a “threshold issue” to be addressed prior to “prudential” considerations. *Hartig Drug Co. Inc. v. Senju Pharm. Co.*, 836 F.3d 261, 269 (3d Cir. 2016) (citation omitted).

As this Court recognized in MTD Opinion 2—decided seven months after

*Rickman* and the actual “most recent” decision in this District—“[t]he Supreme Court’s standing cases have made two principles of law clear: first, a plaintiff must demonstrate standing for each claim he seeks to press; and second, ***class actions do not change the requirements of standing.***” (MTD Opinion 2 at 19 (emphasis added) (citing *DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 337 (2006); *Lewis v. Casey*, 518 U.S. 343, 357 (1996))). Accordingly, the determination of Plaintiffs’ lack of standing to pursue claims under the laws of states in which they do not reside and were not injured cannot be postponed until class certification.

Indeed, the Supreme Court recently added another case bolstering this Court’s ruling. In *TransUnion LLC v. Ramirez*, 141 S. Ct. 2190 (2021), the Court reconfirmed that each plaintiff must have Article III standing to pursue his or her claims—that is, a “personal stake.” *Id.* at 2203 (citations omitted). There, the Court held that 6,332 of 8,185 class members lacked standing where they relied on a “mere risk of future harm” and suffered no “separate concrete harm.” *Id.* at 2209-11. The deficiency is even more stark here, where Plaintiffs have failed at the pleadings stage to supply a single person alleging a “separate concrete harm” under the laws of the 29 states and territories unrepresented by any PELMC plaintiff and the 42 states and territories unrepresented by any PMMMC plaintiff. *See Opp.*, Ex. A at 1-2.<sup>3</sup>

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<sup>3</sup> The revised PELMC and PMMMC accompanying the Reply purport to add new Arkansas Plaintiffs. The Manufacturer Defendants join in and incorporate by reference the Pharmacy Defendants’ arguments in their sur-reply that the revised

The Reply does not even attempt to address this Court's analysis, and Plaintiffs' authorities all commit the same error of treating out-of-state claims differently for standing purposes in the class action context. (*See* Reply at 14-20). This Court correctly found this approach incompatible with Supreme Court precedent. Moreover, this Court has already considered and found innumerable state-by-state conflicts of applicable law in MTD Opinions 3, 4, 5, and 6, further demonstrating the unsuitability of out-of-state standing in this MDL. Nothing in the Reply suggests a reason for this Court to reconsider its well-reasoned decision.

**B. Plaintiffs Should Be Denied Leave to Amend to Assert Claims Against Defendants to Whom Plaintiffs Cannot Trace Their Claims**

MTD Opinion 2 further held that Plaintiffs' claims must be dismissed for lack of standing against each Defendant to whom no Plaintiff can trace an alleged injury. (MTD Opinion 2 at 16-18). Though the PELMC and PMMMC now purport to trace each Plaintiff's purchases to one or more named Defendants, five untraced Defendants remain in the PELMC and eleven remain in the PMMMC. *Opp.*, Ex. A at 3-4. Additionally, Plaintiffs assert state law claims on behalf of putative statewide sub-classes for which no Plaintiff in each represented state can trace an alleged injury to as many as sixteen Defendants. *See id.* at 5-20 (PELMC), 21-26 (PMMMC).

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PELMC and PMMMC are improper and should be stricken. But even if the Court accepts Plaintiffs' untimely amendments, that would still leave 28 and 41 states and territories unrepresented in the PELMC and PMMMC, respectively.

Plaintiffs' Reply fails to address these deficiencies. Much of Plaintiffs' effort is misspent discussing **how** a given Plaintiff's purchases might be traced from the manufacturer to the consumer. (Reply at 7-11). That misses the point. The question is not whether Plaintiffs **can** trace their purchases; it is whether they **have** done so from at least one named Plaintiff to each named Defendant. They have not.

Plaintiffs cannot dispute the continued naming of multiple untraced Defendants in the PELMC and PMMMC. (Reply at 11-12). They concede the "so-called 'peripheral' defendants" should be dismissed, but assert that certain "affiliates" identified as "subsidiaries" of "other named defendants" are properly named. (*Id.* at 11 & n.5). That is wrong. MTD Opinion 2 is clear; Plaintiffs "must allege facts that show their injuries are fairly traceable to **each defendant[s]** conduct." (MTD Opinion 2 at 18 (emphasis added)). Tracing to a parent does not satisfy traceability as to the subsidiary. *See Akaosugi v. Benihana Nat. Corp.*, No. C 11-01272 WHA, 2011 WL 5444265, at \*3 (N.D. Cal. Nov. 9, 2011) ("Plaintiffs have failed to establish Article III standing because they have not demonstrated that the injury to the named plaintiffs is fairly traceable to the subsidiaries."); *Lindsey v. Am. Sec. Ins. Co.*, No. CV 08-126-DLB, 2010 WL 11640212, at \*4 (E.D. Ky. Mar. 29, 2010) (dismissing claims against untraced affiliate companies for lack of standing).

The Reply further attempts to analogize Plaintiffs' claims to an asbestos case against multiple defendants. (Reply at 11-12). But there, the plaintiffs alleged their

injuries “are the proximate result of exposure to” *all* defendants’ asbestos products. *Carlough v. Amchem Prods., Inc.*, 834 F. Supp. 1437, 1455 (E.D. Pa. 1993). Here, each Plaintiff alleges exposure to one or more *specific* Defendants’ valsartan, but there are multiple Defendants to whom *no* Plaintiff has traced an alleged exposure.

The Reply also sets up a straw man, with Plaintiffs insisting they are not required to “identify and trace” at the pleading stage “each and every sale over many years” to “each and every Defendant[.]” (Reply at 10-11). That mischaracterizes Defendants’ position. This Court set the right standard: “[F]or each named defendant, at least one named plaintiff must be able to allege an injury traceable to that defendant.” (MTD Opinion 2 at 17). That excludes all Defendants to whom no named Plaintiff has traced an injury. And, because each Plaintiff only has standing to assert claims under the laws of the state in which that Plaintiff resides and was allegedly injured, *see* § II.A, *supra*, it also excludes all claims under each state’s laws against a Defendant to whom no named Plaintiff in that state can trace an injury. The Reply presents no reason for the Court to reconsider its traceability ruling.<sup>4</sup>

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<sup>4</sup> The Reply also does not respond to the Opposition’s additional arguments that the TPP Plaintiffs fail to allege any “distinct and palpable loss” to the TPP Plaintiffs traceable to the Manufacturer Defendants, and that Plaintiffs’ allegations are insufficient to state a basis for economic recovery of the TPPs’ reimbursed Medicare payments. (*See* Opp. at 16-19). The Reply omits altogether any discussion of traceability with respect to the TPP Plaintiffs’ claims. (Reply at 19-20). Plaintiffs have thus waived traceability (and standing) with respect to the TPP Plaintiffs.

**C. Plaintiffs Should Be Denied Leave to Amend to Assert Breach of Implied Warranty Claims Against Defendants with Whom Plaintiffs Have Failed to Allege Privity**

MTD Opinion 3 found Plaintiffs failed to plead privity between Plaintiffs and the Manufacturer Defendants for breach of implied warranty, as required by two states in the PIMC (Kentucky and Wisconsin) and twelve states in the ELMC and MMC (Alabama, Arizona, Idaho, Kansas, Kentucky, Michigan, North Carolina, Ohio, Oregon, Tennessee, Utah, and Wisconsin). (MTD Opinion 3 at 20-22). Plaintiffs' amendments again fail to supply the requisite allegations of privity.

Rather than cure Plaintiffs' pleadings, the Reply again attempts to reargue the issue, asserting that privity is a "question of fact" that is "ill-suited for resolution" at the pleadings stage under "unsettled ambiguities" in the law. (Reply at 26-31). This Court already considered and rejected these arguments, which Plaintiffs previously asserted along with some of the same authorities in opposing Defendants' motions to dismiss. (*See* ECF No. 577 at 66-71). MTD Opinion 3 held that privity is a *pleading* requirement in the twelve states at issue. (MTD Opinion 3 at 20-22). Once again, Plaintiffs identify no legal issue the Court "overlooked" to warrant reconsideration of its earlier ruling. *K.J.*, 2020 WL 3542305, at \*1.

Regardless, Plaintiffs' authorities do not relieve Plaintiffs of their burden to plead privity. The Reply fails to address most of the authorities cited in the Opposition detailing each state's requirement of privity and the insufficiency of

Plaintiffs’ third-party beneficiary allegations as a substitute for privity.<sup>5</sup> (*See* Opp. at 19-21). Plaintiffs instead cite their own cases from nine of the twelve contested states (Alabama, Arizona, Idaho, Kansas, Michigan, North Carolina, Ohio, Tennessee, and Utah), most of which confirm that an economic loss plaintiff cannot evade privity by asserting a third-party beneficiary theory. (Reply at 29-31).

Even where a third-party beneficiary theory might avoid pleading privity, Plaintiffs have alleged their putative status as “intended third-party beneficiaries” in wholly conclusory terms without factual support. (*See* PPIMC ¶¶ 95, 653; PELMC ¶¶ 149, 237, 655-56, 671-72; PMMMC ¶¶ 494 [sic], 190, 647-48). Such conclusory allegations of third-party beneficiary status are insufficient to state a claim. *See Atlas Commc’ns Tech., Inc. v. DXC Tech. Servs., LLC*, No. 319CV19033BRMDEA, 2020 WL 5105197, at \*3 (D.N.J. Aug. 31, 2020) (dismissing “conclusory statement” that plaintiff was a third-party beneficiary); *Villegas v. Corr. Med. Servs., Inc.*, No. CV 14-7337 (MCA), 2016 WL 3708218, at \*2 (D.N.J. July 12, 2016) (same).

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<sup>5</sup> The Reply does acknowledge adverse authority in Kentucky, but falsely attempts to discard it as “still ambiguous.” Reply at 27-28. There is no ambiguity. Plaintiffs rely on an earlier decision of the Supreme Court of Kentucky that the same Court later rejected because it “mischaracterized” the precedent on which it relied. *See* Reply at 27-28; *Complex Int’l v. Taylor*, 209 S.W.3d 462, 464 (Ky. 2006) (repudiating *Griffin Indus., Inc. v. Jones*, 975 S.W.2d 100, 102 (Ky. 1998)). This is typical of the non-existent “unsettled ambiguities” Plaintiffs attempt to introduce.

**D. Plaintiffs Should Be Denied Leave to Amend to Assert Unjust Enrichment Claims Where Plaintiffs Have Failed to Allege the Absence of an Adequate Legal Remedy**

MTD Opinion 6 identifies thirteen states requiring Plaintiffs to allege the absence of an adequate remedy at law as an element of unjust enrichment. (MTD Opinion 6 at 4, 29-34). The Reply asserts that Plaintiffs “corrected” the PELMC’s unjust enrichment claims to conform to MTD Opinion 6 by adding the conclusory sentence, “no adequate remedy at law exists” to each count. (Reply at 21). Plaintiffs’ amendment is plainly insufficient. As discussed in the Manufacturer Defendants’ Opposition, Plaintiffs’ threadbare legal conclusions and formulaic recitations should be disregarded because they are unsupported by plausible allegations of fact. (Opp. at 28-31 (citing *Ashcroft v. Iqbal*, 556 U.S. 662, 664, 678 (2009))).

Plaintiffs’ own authority reinforces this point, holding that where “the absence of an adequate remedy at law is a *prima facie* element of a claim for unjust enrichment,” Plaintiffs “must allege *facts* which, taken as true, plausibly suggest this element of the claim in order to survive a 12(b)(6) motion to dismiss the unjust enrichment claim[.]” *In re Processed Egg Prods.*, 851 F. Supp. 2d 867, 917-18 (E.D. Pa. 2012) (emphasis added). The detailed factual allegations in that case were not conclusory. *Id.* at 918; *see also* Opp. at 30-31 & n. 6 (collecting cases holding conclusory allegations insufficient). No similar allegations are found here.

The Reply also asserts Plaintiffs are permitted to plead unjust enrichment in



the alternative. (Reply at 21-24). That is not true in all states. *See, e.g., Soule v. Hilton Worldwide, Inc.*, 1 F. Supp. 3d 1084, 1103 (D. Hi. 2014) (“Plaintiff cannot assert an unjust enrichment claim, even in the alternative, because Hawaii law makes clear that the absence of an adequate remedy at law is a necessary prerequisite to maintaining an unjust enrichment claim[.]”). But even where permitted, alternative claims must still satisfy federal pleading standards. *See Irene v. Michael Whaley Interiors, Inc.*, No. 19-cv-14998, 2020 WL 759573, at \*2 (D.N.J. Feb. 13, 2020). Plaintiffs have failed to satisfy their federal pleading obligation of alleging facts supporting a necessary element of their unjust enrichment claims in thirteen states, and, consequently, their amendments are futile.

**E. Plaintiffs’ Should Be Denied Leave to Amend to Add Futile PLA Claims While Retaining Subsumed Common Law Claims**

MTD Opinion 5 held that the Louisiana PLA subsumed claims in the ELMC under Louisiana law, and that the Connecticut, Indiana, Kansas, Louisiana, Mississippi, New Jersey, Ohio, Tennessee, and Washington PLAs subsumed claims in the MMMC under each state’s laws. (MTD Order 5 at 2-4). The PPIMC introduced amendments to address subsumption, while the PELMC and PMMMC did not. The Reply concedes the failure even while complaining that it “elevates form over function”—ignoring the fact that this Court already dismissed Plaintiffs’ subsumed claims in their prior “form.” (Reply at 57). The Reply proposes to address Plaintiffs’ failure by revising the PELMC and PMMMC to add claims under the

applicable states’ PLAs. (*Id.* at 57-58). These new claims are untimely under the Court’s amendment schedule, and therefore impermissible. *See Stallings ex rel. Est. of Stallings v. IBM Corp.*, No. CIV. 08-3121(RBK/JS), 2009 WL 2905471, at \*17 (D.N.J. Sept. 8, 2009) (Kugler, J.) (denying untimely amendment under Rule 15).

There are two other problems with Plaintiffs’ approach. First, unlike the PPIMC, which excluded all subsumed states from its common law counts, *see* PPIMC Counts I-X, XII-XV (charts), the PELMC and PMMMC persist in asserting subsumed claims. The PELMC simply adds alternative Louisiana PLA allegations to each count. (PELMC ¶¶ 630, 642, 649, 668, 692, 708, 725, 741, 745(u), 763(u), 785, 794, 807, 818, 827, 836). And the PMMMC seeks to add a new shotgun count incorporating “all previous and subsequent paragraphs of this Complaint” and purporting to assert claims under nine states’ PLAs “[t]o the extent any claims above are subsumed[.]” (PMMMC ¶¶ 688-725). Thus, Plaintiffs’ edits do not cure the subsumed claims; they improperly add new claims on top of futile, subsumed claims.

Second, as argued in the Opposition, medical monitoring is not a cognizable claim under the nine states’ PLAs, because each PLA excludes medical monitoring or requires present physical harm. (*See* Opp. at 26-27 (collecting cases)). Plaintiffs’ catch-all solution is to assert a “present physical injury” in the form of “cellular and/or genetic injury.” (Reply at 58-60). But the nine states’ PLAs require more—a present, cognizable, and/or manifest injury—not just alleged cellular or genetic

change purportedly increasing future risks. (Opp. at 26-27). A “mere risk of future harm” does not “qualify as a concrete harm” until it manifests into a “separate concrete harm.” *TranUnion*, 141 S. Ct. at 2209-11; *see also In re Zantac (Ranitidine) Prods. Liab. Litig.*, No. 9:20-md-02924, 2021 WL 2682659, at \*11-12 (S.D. Fla. June 30, 2021) (dismissing medical monitoring claims where plaintiffs “failed to clearly plead just how much [NDMA] exposure the [p]laintiffs received and how much exposure is needed to warrant the remedy of medical monitoring”).

**F. Plaintiffs Should Be Denied Leave to Amend to Add an Unauthorized “Official Compendium” Theory**

Lastly, the Reply makes light of Plaintiffs’ unauthorized addition of a new “official compendium” theory, asserting it is nothing more than “additional facts and clarifications.” (Reply at 4-6). But Plaintiffs’ earlier passing mentions of the “Orange Book” and the FFDCA’s “official compendium” provision did not articulate the same claim at all, as the Opposition explains. (*See* Opp. at 32-34). Regardless, Plaintiffs’ supposed “clarifications” are futile because the Orange Book is not an “official compendium” and the USP contained no “compendial standards” relating to nitrosamines at the time. (Opp. at 34-37). Thus, whether a new theory or a “clarification,” Plaintiffs’ “official compendium” theory cannot state a claim.

The Reply also erroneously insists MTD Opinion 1 governs the new preemption issue arising out of Plaintiffs’ attempted private enforcement of the Orange Book. That ignores on-point authority that Plaintiffs’ newfound reliance

upon alleged non-compliance with “Orange Book standards” and “Orange Book requirements” constitutes an impermissible attempt to privately enforce the FFDCA. (Opp. at 37-39). For each of these reasons, Plaintiffs’ new “official compendium” theory is futile and prejudicial, and leave to amend should be denied.

### **III. CONCLUSION**

The Court’s MTD Opinions and MTD Orders gave Plaintiffs a clear roadmap to follow in amending their Master Complaints. Plaintiffs disregarded the Court’s guidance, failed to cure the standing and pleading defects identified by the Court, and added new amendments not contemplated by the Court’s rulings. Unable to justify Plaintiffs’ amendments in light of the Court’s unambiguous guidance, Plaintiffs’ Reply instead asks the Court to revisit its rulings based on the same arguments and same authorities the Court previously rejected—without even attempting to meet the rigorous standard for reconsideration. Plaintiffs’ amendments are futile, and the Manufacturer Defendants respectfully request that this Court deny the Motion to Amend, or, in the alternative, grant the Motion to Amend subject to the conditions and limitations set forth in the Opposition.

Dated: August 2, 2021

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I hereby certify that on this 2nd day of August, 2021, I caused a true and correct copy of the foregoing to be filed and served upon all counsel of record by operation of the Court's CM/ECF system.

/s/ Lori G. Cohen

Lori G. Cohen